

Butler, Jennie C

From: Sheehan, Joseph M.
Sent: Wednesday, May 29, 2002 8:40 AM
To: 'BULLELKMAN@aol.com'; Dockets, FDA; brownchas@erols.com
Cc: Fourpawsca@aol.com; GRUFFY3@aol.com
Subject: RE: Additional comments about New 60-Day Period - Docket Number #01N-0067

Q. Will e-mails and letters sent to the FDA after May 21, 2002 and until the new comment period reopens be routed to Docket Number #01N-0067?

A. Yes.

Q. Will Arne Hanson's letter at the end of my letter that was sent to the FDA on May 28, 2002 be routed to Docket Number #01N-0067 even though it is between the comment periods? Please see Arne's letter at the end of my letter.

A. Yes

Q. Will Merrilee Pettinger's passionate letter about the dangers of mercury fillings to her own life, her granddaughter's life and her friends' lives be routed to the Docket Number #01N-0067? Her e-mail is about mercury fillings, so can we (you) trust the Public Health Advisor has routed it to Docket Number #01N-0067?

3. I see that Merrilee Pettinger's passionate letter with comments about the dangers of mercury in dental fillings does not have a docket number, but the subject matter of the letter is very clear. Was it route to Docket Number #01N-0067?

A. I don't know but I see to it that it gets there.

Q. Are you the right person that can tell us if we can have public hearings around the country on mercury in dental fillings? If you are not the correct person, who can we contact to ask that question?

A. FDA is considering your request along with another request for another meeting of the advisory committee. We will respond to your request but I cannot tell you when or in what format.

Q. Did you know that Docket Number #01N-0067 is not listed on Dockets Management webpage?

A. As noted there, not all dockets are listed on that page.

Q. Because many could not find the docket number, we used the FDA e-mail provided on the webpage fdadockets@oc.fda.gov, is that the correct e-mail address to use?

A. That is the correct address to use.

Q. VERY IMPORTANT question - If FDA places the topic of mercury dental fillings on the Dockets Management page, can we still use fdadockets@oc.fda.gov during the next comment time and all e-mails will be routed to Docket Number #01N-0067?

A. To assure that your comments are considered, you should send them to Dockets Management Branch at one of the given addresses and include Docket Number #01N-0067 at the top of the letter/e-mail.

01N-0067

ANSI

Thanks you.

Joseph M. Sheehan,
Chief, Regulations Staff
Phone 301-827-2974
Fax 301-594-4795
jms@cdrh.fda.gov

-----Original Message-----

From: BULLELKMAN@aol.com [mailto:BULLELKMAN@aol.com]
Sent: Wednesday, May 29, 2002 4:47 AM
To: JMS@CDRH.FDA.GOV; FDADockets@oc.fda.gov; brownchas@erols.com
Cc: Fourpawsca@aol.com; GRUFFY3@aol.com
Subject: Additional comments about New 60-Day Period - Docket Number
#01N-0067

Dear Mr. Sheehan,

Per my voice mail message, thank you for your prompt reply but I still
have
some questions and I appreciate you taking the time to answer them for
me.
My questions were obviously a little confusing so I will try again to be
more
precise and to the point.

Thanks,
Mary Ann Newell

MY QUESTION:

1. I trust that the FDA will use the same docket number -Docket Number
#01N-0067 for the new 60-Day Period. Please let me know if I am right
or
wrong on this comment. Thank you.

YOUR ANSWER:

The docket number for the proposed rule on classification of dental
amalgams
will remain 01N-0067, when the comment period is reopened. The
docket
number for the guidance document will remain 01D-0064.

MY REPLY: THANK YOU!

MY QUESTION:

2. I will tell family and friends to continue to send in their comments
using Docket Number #01N-0067 during this time between comment periods
and
their comments will be valued by the FDA for this important topic and
routed
to the proper person for recording in the public records. Please let me
know
if I am right or wrong on this comment. Thank you.

MY NEW QUESTION:

Will e-mails and letters sent to the FDA after May 21, 2002 and until

the new
comment period reopens be routed to Docket Number #01N-0067?

MY NEW QUESTION:

Will Arne Hanson's letter at the end of my letter that was send to the
FDA on
May 28, 2002 be routed to Docket Number #01N-0067 even though it is
between
the comment periods? Please see Arne's letter at the end of my letter.

Thank you.

MY QUESTIONS:

3. I trust that the FDA will route any correspondence regarding mercury
in
dental fillings to Docket Number #01N-0067 even if the docket number is
not
on the e-mail or letter. Please let me know if I am right or wrong on
this
comment. Thank you.

4. I trust that any member of FDA that gets personal correspondence on
this
vital topic of the mercury in dental fillings will forward that
information
so FDA can review it and make it part of the public records regarding
this
important topic of mercury in dental fillings. Please let me know if I
am
right or wrong on this comment. Thank you.

YOUR ANSWER:

As is our practice, we at FDA will do our best to make sure that all
relevant
documents are placed in the docket.

MY REPLY: Thank you for this reassurance with this comment regarding
these
two questions.

MY NEW QUESTIONS:

1. Will Merrilee Pettinger's passionate letter about the dangers of
mercury
fillings to her own life, her granddaughter's life and her friends'
lives be
routed to the Docket Number #01N-0067?
2. Her e-mail is about mercury fillings, so can we (you) trust the
Public
Health Advisor has routed it to Docket Number #01N-0067?
3. I see that Merrilee Pettinger's passionate letter with comments about
the
dangers of mercury in dental fillings does not have a docket number, but
the
subject matter of the letter is very clear. Was it route to Docket
Number
#01N-0067?
Please see Merrilee's letter at the end of my letter. Thank you.

MY QUESTION:

5. I would like to invite the FDA to come out and talk to the American

public
on this important topic of mercury dental fillings. I know that it
would be
an "EYE OPENER" for the FDA. Please help us to get the FDA to hold
public
hearings around the country on this topic of mercury dental fillings. I
would like a comment, if you have any comment on this topic of public
hearings. Thank you.

MY NEW QUESTION:

1. Are you the right person that can tell us if we can have public
hearings
around the country on mercury in dental fillings?
2. If you are not the correct person, who can we contact to ask that
question? Thank you

YOUR COMMENT:

To be certain that they will be included in the docket, comments should
be
submitted as stated in the Federal Register:

"Submit written comments on the draft guidance [or proposed rule] to
the
Dockets Management Branch (HFA-305), Food and Drug Administration, 5630
Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments
to
<http://www.fda.gov/dockets/ecomments>. Comments should be identified with
the
docket number found in brackets in the heading of this document."

NEW QUESTIONS:

1. Did you know that Docket Number #01N-0067 is not listed on Dockets
Management webpage?
2. Because many could not find the docket number, we used the FDA e-mail

provided on the webpage fdadockets@oc.fda.gov, is that the correct
e-mail
address to use?

3. VERY IMPORTANT question - If FDA places the topic of mercury dental
fillings on the Dockets Management page, can we still use
fdadockets@oc.fda.gov during the next comment time and all e-mails will
be
routed to Docket Number #01N-0067 ?

I appreciate you taking the time to respond back to me.

Thank you again,
Mary Ann Newell
Manager of the Files for Consumers of Dental Choice
Phone - 360-694-5770

Subj: Docket Number 01N-0067
Date: 5/28/2002 7:07:48 PM Pacific Standard Time
From: AuArne

To: fdadockets@oc.fda.gov

CC: BULLELMAN, benton_do@leg.wa.gov

"Docket Number 01N-0067 -----AGAINST the FDA rule

I think that it is absolutely ridiculous that the FDA would consider calling mercury amalgam tooth fillings a "safe" dental practice...Your advisory panel hasn't met for eight years and has not considered any of the latest findings

I was never told that "silver" or amalgam fillings contain mercury and now at the age of 59, I have dangerously high levels of mercury toxicity which has played havoc on my health.

The FDA should hold public hearings and hear from the thousands of people who, like me, are having severe health problems from mercury toxicity related illnesses.

It appears that your FDA rule is written to shore up the old dental establishment and the AMA. It also appears that money and political power is

more important than the health of the American public.

I would urge you to have further study and public hearings on the matter.

I would also urge your panel to study current information regarding the dangers of mercury fillings rather than to use information which was outdated

10 years ago. Perhaps there should be some New faces on the Old panel. Therefore I am AGAINST the FDA rule..

Sincerely,
Arne Hanson.

Subj: 05-470 bjl zd Comments to the FDA
Date: 5/28/2002 6:27:13 AM Pacific Standard Time
From: BJL@CDRH.FDA.GOV

To: mmp2157@aol.com

CC: DSMA@CDRH.FDA.GOV

Sent from the Internet (Details)

This is in response to your email below to the Food and Drug Administration (FDA) regarding mercury in dental amalgams.

Thank you for taking the time to write the FDA with your concerns. You can find our most current information/position on mercury in dental amalgams on our web site at <http://www.fda.gov/cdrh/consumer/amalgams.html>

Once again, thank you for writing.

Sincerely,

Bonnie Alderton
Public Health Advisor
Consumer Staff
Center for Devices and
Radiological Health
BJL@CDRH.FDA.GOV

THANK YOU!

Your 100% satisfaction is our #1 goal and your feedback is important to us.

If for any reason you are not completely satisfied or have a comment to make, please contact us toll-free at:
1-800-638-2041, ext. 136 or email us at:
dsmica@cdrh.fda.gov

Division of Small Manufacturers, International and Consumer Assistance
Center for Devices and Radiological Health
Food and Drug Administration
Department of Health and Human Services

-----Original Message-----

From: WEBO@CDRH.FDA.GOV [mailto:WEBO@CDRH.FDA.GOV]
Sent: Sunday, May 19, 2002 1:17 AM
To: DSMA@CDRH.FDA.GOV
Subject: DSMICA Email Form Response

Name: Merrilee Pettinger
Phone Number: 503 698 6285
Fax Number: 503 698 6285
Email Address: mmp2157@aol.com

Mailing Address:
po box 2157 se sunnyside road #11
clackamas oregon 97015

Questions/Comments:

Please outlaw mercury amalgams. I suffered a lifetime of immune related health problems that started with my first amalgam filling over 40 years ago.

It began with a rash a few days after my first filling and never ended.

My granddaughter had an amalgam filling put in against her parents wishes and

fell ill within a few days and suffered a year of constant fevers, flu-like

symptoms, chronic sore throat, strep throat, rashes untill they had the mercury amalgam removed. She is better though her immune system has not fully

recovered. It appears amalgam is very cheap to put in and profitable.

So,

greedy or ignorant dentists with no integrity buy it up and put it in without

regard to patient health. Dental insurance companies profit from cheap and

lethal amalgams. My attorney and his 16 year old daughter both got thyroid

cancer within 3 months of having amalgam fillings. There is a growing movement of dentists against amalgams who have watched their fellow dentists

die premature death! s after suffering terrible amalgam related illnesses. The EPA has outlawed cremations in Clackamas County with amalgams

intact. They must be removed before cremation now. At one time Clackamas

County had the highest rate of breast cancer. EPA wonders of the link to mercury vapors from all the cremations as we have many cemeteries. I pray you heed these obvious signs of danger to the health of the American public. The growing movement of American public made ill by amalgams are past thinking the FDA a credible source of accurate information. We believe some of you mean well and want only the best for us, some are ignorant or too lazy/arrogant to inform themselves, some of you think you already know everything, and some of you are only into making a name and profit for yourselves without regard to our health. It is only a matter of time before you lose your credibility on the amalgam issue with the rest of the public. All my family and friends, and church group, and choir, all know! amalgams are dangerous poison. That is why it is stored in lead containers before and after use. Again, please outlaw amalgams. Set aside your unfactual, unsubstantiated, unscientific facts you are relating. Everyone knows the reports stating amalgams to be safe are put out by those making a profit on them. The age of stupid consumers is over. Please put an end to the era of amalgams. It went out with schoolchildren's radiated milk, thermiseal in vaccines, and nuclear waste being OK to dump anywhere. Sincerely Merrilee Pettinger